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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Michael Horstmann et al.

Serial No.: 10/581,867

Filed: June 5, 2006 / Conf. No. 3928

Title: INHALER FOR BASIC PHARMACEUTICAL AGENTS AND

METHOD FOR THE PRODUCTION THEREOF

Examiner: / Art Unit: _

Attorney File: RO4244US (#90568)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

LETTER

Sir:

Submitted herewith for inclusion in the record for the referenced patent application is a copy of an English translation of the "International Preliminary Report on Patentability". Our client advises that the date of completion of the report is February 27, 2006.

Respectfully submitted,

By:____

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Certificate of Mailing

I hereby certify that this document, and anything indicated as being attached or enclosed, is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date noted below.

Christine Kotran: Christine Robran

Date: January <u>4</u>, 2007

PATENT COOPERATION TREATY

PCT

TRANSLATION INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applican	t's or agent's file reference								
	2003/008 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416						
Internation	onal application No.	International filing date (day/month/yea	Priority date (day/month/year)						
PCT	/EP2004/012947	16.11.2004	05.12.2003						
International Patent Classification (IPC) or national classification and IPC									
A241	F47/00, A61 M15/0	6							
Applicant									
LTS LOHMANN THERAPIE-SYSTEME AG									
		f							
1.	This report is the international preliunder Article 35 and transmitted to the	· ·	by this International Preliminary Examining Authority						
2.	This REPORT consists of a total of	7 sheets, i	ncluding this cover sheet.						
3.	This report is also accompanied by A	NNEXES, comprising:							
	K-7	to the International Bureau) a total of	5 share as fallows.						
	•	-							
	sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).								
	sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.								
	b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))								
, containing a sequence listing and/or tables									
,	related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see								
Section 802 of the Administrative Instructions).									
4.	This report contains indications relat	ing to the following items:							
	Box No. I Basis of th	e report	•						
	Box No. II Priority								
		ishment of opinion with regard to povelty	v. inventive step and industrial applicability						
	Box No. IV Lack of unity of invention								
	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement								
	Box No. VI Certain documents cited								
	Box No. VII Certain defects in the international application								
	Box No. VIII Certain observations on the international application								
Date of	Date of submission of the demand Date of completion of this report								
N									
Name a	nd mailing address of the IPEA/EP	Authorized office	Authorized officer						
		·	•						
Facsimi	le No.	Telephone No.	Telephone No.						

International application No.
PCT/EP2004/012947

Box	No. I	Basis of the report					
1.		to the language, this report is based on the internation der this item.	nal application in the language in	which it was filed, unless otherwise			
	This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of: international search (Rule 12.3 and 23.1(b)) publication of the international application (Rule 12.4) international preliminary examination (Rule 55.2 and/or 55.3)						
2.	receiving O this report):	Ito the elements of the international application, this in a liftice in response to an invitation under Article 14 are ternational application as originally filed/furnished escription:	report is based on (replacement s	riginally filed" and are not annexed to			
	pages	1-18		as originally filed/furnished			
	pages	*	received by this Authority on				
	pages	*	received by this Authority on	•			
	the cl			11 (2) 1/6 3 . 1			
	nos.			as originally filed/furnished			
	nos.*	1-23	as amended (together received by this Authority on	r with any statement) under Article 19 16.08.2005 with letter of 11.08.2005			
	nos.*		received by this Authority on				
	\square						
	sheet	rawings: -s 1/5-5/5		as originally filed/furnished			
	sheet	•	received by this Authority on				
	· .		received by this Authority on				
	sheet						
	a seq	uence listing and/or any related table(s) - see Supplem	ental Box Relating to Sequence I	Listing.			
3.	The amendments have resulted in the cancellation of:						
1		the description, pages					
		the claims, nos.		·			
		the drawings, sheets/figs					
		the sequence listing (specify):		<u> </u>			
		any table(s) related to sequence listing (specify):		· .			
4.		report has been established as if (some of) the amend have been considered to go beyond the disclosure as fi					
		the description, pages	<u></u>				
		the drawings, sheets/figs					
		the sequence listing (specify):					
		any table(s) related to sequence listing (specify):	· · · · · · · · · · · · · · · · · · ·				
*	If item 4 a	applies, some or all of those sheets may be marked "sup	perseded."				

International application No.

PCT/EP2004/012947

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of: the entire international application claims Nos. 7,8,22,23 because: the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that on meaningful opinion could be formed (specify): See Supplemental Box
because: the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): the description, claims or drawings (indicate particular elements below) or said claims Nos. 7,8 are so unclear that no meaningful opinion could be formed (specify):
the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): the description, claims or drawings (indicate particular elements below) or said claims Nos. 7, 8 are so unclear that no meaningful opinion could be formed (specify):
the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): the description, claims or drawings (indicate particular elements below) or said claims Nos. 7,8 are so unclear that no meaningful opinion could be formed (specify):
the description, claims or drawings (indicate particular elements below) or said claims Nos. 7,8 are so unclear that no meaningful opinion could be formed (specify):
the description, claims or drawings (indicate particular elements below) or said claims Nos. 7,8 are so unclear that no meaningful opinion could be formed (specify):
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are so unclear that no meaningful opinion could be formed (specify):
See Supplemental Box
\mathbf{i}
the claims, or said claims Nos are so inadequately supported
by the description that no meaningful opinion could be formed.
no international search report has been established for said claims Nos. 22,23
the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
the written form has not been furnished
does not comply with the standard
the computer readable form has not been furnished
does not comply with the standard
the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
See Supplemental Box for further details.

International application No.								
PCT/EP2004/012947								

Box			cle 35(2) with regard to novelty, inventive step or industrial applicability; orting such statement				
1.	Statement	A. <u>s</u> .					
-	Novelty (N)	Claims _	1-6, 9-21	YES NO			
	Inventive step (IS)	Claims _	1-6, 9-21	YES NO			
		Claims _		— NO			
	Industrial applicability (IA)	Claims _	1-6, 9-21	YES			
	•	Claims _		NO			
2.	Citations and explanations (Rule	70.7)					
	Reference is ma	de to	the following documents:				
	D1: US 4765348						
	D2: US 4800903			·			
	D3: US 5746227						
	D4: GB 1017032	•					
				•			
	Document D1 dis	closes	s the features of the preamble of				
	claim 1 (see fi	gure 3	3; column 2, lines 31-35) and the				
	additional feat	ures c	of the following dependent claims:				
	- claim 2:	S	see column 2, lines 48-50				
:	- claim 5:	S	see column 2, line 39				
	- claim 6:	S	see column 2, line 33	•			
	- claim 10,	11: s	see column 2, lines 55-59				
			see column 2, line 54.				
	•			-			
į	Document D3 dis	scloses	s the features of the preamble of				
	claim 1 (see claim 30; column 4, lines 55-57) and the						
	additional feat	cures o	of the following dependent claims:				
	- claims 3,	4:	see column 5, line 8				
	- claim 9:	;	see column 2, line 9.				

International application No.
PCT/EP2004/012947

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Document D3 discloses the features of the preamble of claim 1 (see column 2, lines 17-20).

The features of the characterizing part of claim 1 are not known from or suggested by the available prior art.

Claims 2-6 and 9-17 are dependent on claim 1 and are therefore likewise considered novel and inventive. The method claims 18-21 relate to a device according to claim 1 and are therefore likewise considered novel and inventive.

International application No.
PCT/EP2004/012947

Box	No. VII	Certain defe	cts in the inter	national applic	ation					
The	following o	lefects in the form	or contents of	the international	l application ha	ve been no	oted:			
	The :	features	of the	claims	are no	t fo	llowed	d by r	reference	9
	signs	s placed	betwee	en paren	theses	(PCT	Rule	6.2 (t)).	
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						-				

International application No.
PCT/EP2004/012947

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box III.1

Claims 7 and 8 do not meet the requirements of PCT Article 6 because the subject matter for which protection is sought is not clearly defined. These claims attempt to define the subject matter in terms of the results to be achieved, but in so doing merely state the problem to be solved, without specifying the technical features necessary to achieve the result.

Claims 22 and 23 concern a method for the treatment of the human or animal body by therapy (PCT Rule 39.1(iv)), that is to say smoking cessation and the administration of the medical drugs Selegilin and mecamylamine (see page 2, lines 21 to 27).